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Seeking Shelter During Uncertain Times: Assessing the Federal Quality Assurance Privilege

By: Donna J. Senft, Virginia B. Evans and John S. Linehan

As a critical element in a nursing facility's internal controls, a quality assurance and assessment (QA) committee must comply with policies designed to effectively monitor and enhance quality of care standards. In order to promote meaningful quality reviews, such policies must reflect careful consideration of the scope and power of the quality assurance privilege, which protects certain QA-related materials from disclosure. This article summarizes the case law addressing the scope of the QA privilege and provides guidance for nursing facilities that must operate QA committees in an increasingly hostile regulatory environment.

Federal Nursing Home Reform Act

In 1987, the United States Congress passed the Federal Nursing Home Reform Act (FNHRA, or the "Act") which instituted a comprehensive regulatory regime governing nursing facilities that participate in Medicare and Medicaid programs. Aimed at improving the quality and uniformity of care, FNHRA mandates that all participating facilities abide by certain conditions of oversight and inspection. For enforcement purposes, states are enlisted under the Act to conduct annual surveys designed to uncover deficient quality of care. Reports of noncompliance may be forwarded to the Secretary of Health and Human Services, who is authorized to penalize substandard facilities by denying payments, imposing civil monetary fines, or by appointing temporary management to oversee facility operations.

A focal point in FNHRA's regulatory apparatus is the requirement that participating nursing facilities establish and maintain QA committees, which meet periodically to effect "appropriate plans of action to correct identified quality deficiencies." See 42 U.S.C. § 1395i-3(b)(1)(B) (addressing skilled nursing facilities); § 1396r(b)(1)(B) (addressing nursing facilities). Nursing facilities enjoy wide discretion in structuring QA committee policies and procedures. In addition, to ensure that QA committees perform their functions in a forthright and thorough manner, the Act affords a privilege against disclosure, whereby "[a] State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph." *Id.*

Assessing the Scope of the Federal Quality Assurance Privilege

Despite its far-reaching practical significance, few courts have opined on the scope of the federal quality assurance privilege, and authorities that have addressed the issue have utilized divergent interpretative approaches. Nevertheless, regardless of the scarcity and uncertainty of existing law, courts have converged behind the view that the privilege must be narrowly construed.

As the first to rule on the issue, the Missouri Supreme Court determined that the privilege only protects a "committee's own records—its minutes or internal working papers or statements of conclusions—from discovery." *State of Missouri ex rel. Boone Retirement Center, Inc. v. Hamilton*, 946 S.W.2d 740, 743 (Mo. 1997). In so ruling, the court defined the privilege as "exceedingly narrow," and added that "[n]o honest reading of the statute . . . can extend the statute's privilege to records and materials generated or created outside the committee and submitted to the committee for its review." *Id.* The Boone court viewed the privilege in a bright-line manner, as only protecting internally produced QA committee documents.

The Boone approach was recently cited in two federal court decisions that address the privilege. Jewish Home of Eastern PA v. CMS, 413 Fed. Appx. 532, 534–35 (3d Cir. 2011); *Brown v. Sun Healthcare Group, Inc.,* 2008 WL 1751675 (E.D. Tenn. Apr. 14, 2008). In both cases, the issue presented was whether the privilege extended to incident reports—documents that describe the factual circumstances

of accidents or events involving facility residents. Citing Boone, both courts summarily determined that the reports were not protected against disclosure because they were external documents that were merely forwarded to the QA committee for its review. The Third Circuit Court of Appeals emphasized the "contemporaneous" and "routinely-generated" nature of such reports, as distinguished from the minutes, internal papers, or conclusions normally produced by a QA committee. *Jewish Home of Eastern PA*, 413 Fed. Appx. at 534–35.

In other decisions, state courts have eschewed the formulaic approach advanced in *Boone* in favor of a more nuanced interpretation that accounts for policy considerations underlining the privilege. In the *Matter of Subpoena Duces Tecum, Jane Doe*, the New York Court of Appeals stated that the key question in assessing whether the privilege applies is not who authored the documents at issue, but instead their relatedness to quality assurance purposes. 787 N.E.2d 618, 619 (N.Y. 2003). Accordingly, the court determined that the privilege applied to "any reports generated by or at the behest of a quality assurance committee for quality assurance purposes," and that such requested records may include, "compilations, studies or comparisons of clinical data derived from multiple [clinical] records. . . ." *Id.* at 623. Any facility records that may be required to be created under state law for purposes unrelated to quality assurance—which could include accident and incident reports—would not receive protection, even where they are reviewed, duplicated, or even created by a QA committee. *Id.* at 622. The court concluded that "the federal protection is narrow" and that protection only extended to documents that bear some "express relationship to quality assurance procedures." *Id.* at 622, 623; *see also Spakoski v. Amsterdam Memorial Hospital Skilled Nursing Facility,* 789 N.Y.S.2d 408, 409-10 (2005) (following Jane Doe and concluding that an incident report was not privileged because it was created pursuant to state regulatory requirements and was unrelated to quality assurance purposes).

The functional approach proposed in *Jane Doe* was subsequently affirmed by the Superior Court of Massachusetts, when it held that survey reports generated by the Massachusetts Department of Public Health deserved privileged status, despite the fact that they were not prepared "by or at the behest of" a nursing facility's QA committee. *Evans v. Quaboag on the Common, Inc.,* 2009 WL 5698096, at *3

(Mass. Super. Ct. 2009). The court explained that the survey reports were "compiled for the purpose of assisting nursing facilities in determining whether certain areas related to patients' quality of care need to be addressed" and were therefore "generated for the express purpose of aiding the committee in achieving its goals." *Id.* In so ruling, the Evans court reaffirmed the reasoning in *Jane Doe* that focused upon whether the subject records were germane to the QA process. The court concluded that such an approach was "consistent with the general principle of cloaking quality assurance materials in confidentiality to encourage thorough and candid peer review." *Id.*

At first glance, the functional interpretation of the quality assurance privilege appears broader in that it would shield documents created in the furtherance of a QA committee's review, even if they came from an external source. On the other hand, however, the functional approach would not protect internal documents created by a QA committee that were not directly related to quality assurance measures. For instance, in *Hale v. Odd Fellow & Rebekah Health Care Facility,* 728 N.Y.S.2d 649 (N.Y. Sup. Ct. 2001) the court determined that information contained in the minutes of a QA committee's regular meeting were not privileged when they referred to the nursing facility's inspection activities and security measures, since they are unrelated to resident care and treatment. *Id.* at 651. In addition, the minutes of another QA committee meeting were ordered to be disclosed because the meeting involved outside parties and matters unrelated to internal quality assurance review, meaning that the committee had effectively waived any privilege protections. *Id.* at 651–52.

Seeking Shelter Under the Federal Quality Assurance Privilege

Because of the scarcity and somewhat disparate nature of the relevant case law, it is difficult to formulate a definitive picture of the scope of the federal quality assurance privilege. Nevertheless, certain conclusions can be deduced from precedent that may guide a facility's compliance efforts. On the one hand, it is clear that records generated by a QA committee as part of its deliberative activities fall safely within the privilege's protective core. Generally, this would afford shelter to the minutes, internal working papers, and statements of conclusions made by a QA committee that relate to quality assurance matters. At the other end of the

spectrum, external documents routinely produced in accordance with legal requirements, such as incident reports which may be required to be created under state law, generally will not be protected, even when they are forwarded to a QA committee for its review.

The issue of whether protection applies to external documents, produced either at the behest of a QA committee, or in the furtherance of its duties, remains a gray area. A functional interpretation of the privilege would permit the withholding of such documents so long as they bear a close nexus to quality assurance purposes. However, unless or until more courts adopt this interpretation, nursing facilities should not assume that quality assurance reports created by outside parties, such as consultants, are protected. Likewise, QA committees should remain vigilant of all matters discussed during its meetings; committee records may not receive automatic protection merely because they are generated internally. A facility could waive the privilege in circumstances where its committee invites third parties or discusses matters wholly unrelated to quality assurance review.

Guidance for Availing the Privilege

Although the scope of the federal quality assurance privilege is limited and somewhat uncertain, its protective force is not insignificant. There are important and effective procedures that nursing facilities may follow to ensure that QA documents are kept confidential. In addition, many states provide similar privileges, and facilities should align their procedures to take advantage of available protections under both state and federal law. In order to ensure maximum shelter, nursing facilities are invited to consider the following practice pointers.

- Nursing facilities should draft policies that broadly define the matters subject to review by its QA committees. Such policies should comprehensively identify the types of documents and records that are created by, or at the request of, the QA committee. For example, QA documents may include QA committee minutes, forms used for conducting billing compliance or quality of care audits, or forms used to record credentialing decisions.
- In addition to identifying which documents need to be protected, facility QA practices should be designed to protect these documents by:

- Identifying a person (by position, but not by name) to be responsible for control over QA committee records and properly training the individual regarding how to maintain confidentiality of the QA records;
- Setting aside a separate, labeled and secure area for storage of QA committee records;
- Clearly labeling all forms and other documents (QA meeting minutes, audits, investigation reports, etc.) created by or at the request of the QA Committee as confidential and privileged;
- Refraining from discussing QA activities and specific incidents in public documents (e-mail correspondence, resident council meetings, etc.).

- When retaining outside consultants, QA committees should delineate the scope of the consultants' services in the engagement letter. The relationship between the QA committee and the consultants should remain confidential and consultants should reference the quality assurance privilege in all documentation and correspondence forwarded to the QA committee.
- Facilities should recognize the risk that incident reports—even those properly created and maintained as confidential QA documents—may be subject to disclosure. As a result, to the extent that a facility uses incident report forms, they should be carefully segregated and not combined with the investigation report form.
- Before investigating an incident, facilities should determine who should conduct the investigation, including whether the incident is one that requires legal counsel to be involved in the investigation to potentially receive additional protection under the attorney-client privilege.
- Facility policies should also identify the information to be documented in medical records following an incident. In particular, the medical records should reflect the pertinent facts regarding what happened, the medical status of the resident before and after the incident, any medical care rendered in response to the incident, and who was notified regarding the incident and when the notification occurred. The medical record should not include a reference to any incident report or provide an overview of the investigation analysis.